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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,217	12/21/2001	Eric N. Olson	UTSD:695US	3415

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EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,217	OLSON ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-126 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-126 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-43 and 81, drawn to polynucleotide, expression cassette, transformed host cell, method of use of the host cell to make myocardin and method of expressing a myocardin polypeptide, classified in class 435, subclass 69.1.

II. Claims 44-47, drawn to peptides and fusion proteins, classified in class 530, subclass 350.

III. Claims 48-77, drawn to method of using the expression cassette to transform fibroblasts into cardiomyocytes, classified in class 435, subclass 455.

IV. Claims 78-80, drawn to method of stimulating cardiac tissue regeneration, classified in class 514, subclass 44.

V. Claims 82-84, drawn to antibodies, antisera and hybridomas, classified in class 435, subclass 326.

VI. Claims 85-92, drawn to transgenic animal, classified in class 800, subclass 8.

VII. Claims 93-98, drawn to method of gene therapy, classified in class 514, subclass 44.

VIII. Claim 99, drawn to method of treating a heart disease using antisense nucleic acid, classified in class 514, subclass 44.

IX. Claims 100-103, drawn to methods of decreasing mortality or morbidity in a subject with heart failure comprising inhibiting the function of myocardin, classified in class 514, subclass 44.

X. Claims 104-116, drawn to method of screening for a candidate substance for an effect on myocardin regulation of cardiomyocyte development, classified in class 435, subclass 6.

XI. Claims 117-120, drawn to method of screening for a modulator of myocardin expression, classified in class 435, subclass 6.

XII. Claims 121-126, drawn to method of screening a candidate substance for myocardin binding activity, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. The polynucleotides of group I are related to the proteins of group II by virtue of the fact that the polynucleotides code for the proteins. The polynucleotide molecules have utility for the recombinant production of the proteins in a host cell. Although the polynucleotides and the proteins are related, since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by other and materially distinct processes, such as purification from the

natural source. Further, the polynucleotides can be used for processes other than the production of proteins, such as nucleic acid hybridization assays.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the expression cassette could be used in a materially different process such as an expression assay in a bacterium.

5. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antisense nucleic acid could be used in a materially different process such as in a hybridization assay.

6. The polynucleotides of group I and the antibodies of group V are related by virtue of the proteins that are encoded by the polynucleotides and necessary for the production of the antibodies. However, the polynucleotides themselves are not

necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

7. The host cells of group I and the transgenic animal of group VI are related by virtue of the polynucleotides contained within the expression cassette. However, the host cells are used for different purposes from the transgenic animal, for example, for the large-scale production of the proteins encoded by the polynucleotides and both have different compositions and functions. Therefore, these inventions are distinct.

8. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides could be used in a materially different process such as large-scale production of the encoded protein.

9. Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

polynucleotides could be used in a materially different process such as large-scale production of the encoded protein.

10. Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the complementary strands of the polynucleotides could be used in a materially different process such as a hybridization assay.

11. Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides could be used in a materially different process such as large-scale production of the encoded protein.

12. Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides could be used in a materially different process such as a hybridization assay.

13. The polynucleotides of group I are related to the method of using the proteins of group XII by virtue of the fact that the proteins are encoded by the polynucleotides. The inventions are distinct, however because the polynucleotides are not used in the screening method and are not necessary for the screening method. Therefore, the inventions are distinct.

14. The peptides of group II are related to the method of using the expression cassette to transform fibroblasts into cardiomyocytes of group III by virtue of the fact that the polynucleotides in the expression cassette encode the peptides. The inventions are distinct, however because the peptides are not used in the method of using the expression cassette to transform fibroblasts into cardiomyocytes and are not necessary for that method. Therefore, the inventions are distinct.

15. The peptides of group II are related to the method of stimulating cardiac tissue regeneration of group IV by virtue of the fact that the antisense polynucleotides used in the method are the opposite strands of the polynucleotides that encode the peptides. The inventions are distinct, however because the peptides are not used in the method

of stimulating cardiac tissue regeneration and are not necessary for that method. Therefore, the inventions are distinct.

16. The peptides of group II are related to the antibodies of group V by virtue of being the cognate antigens necessary for the production of antibody. Although the peptides and antibodies are related due to the necessary steric complementarity of the two, they are distinct inventions because the peptides can be used in other, materially different processes from the production of antibody such as in pharmaceutical compositions in its own right. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

17. The peptides of Invention II and the transgenic animal of Invention VI are unrelated products that differ in structure and function. Therefore, Inventions II and VI are patentably distinct.

18. The peptides of group II are related to the method of gene therapy of group VII by virtue of the fact that the polynucleotides used in the method encode the peptides. The inventions are distinct, however because the peptides are not used in the method of gene therapy and are not necessary for that method. Therefore, the inventions are distinct.

19. The peptides of group II are related to the method of treating a heart disease of group VIII by virtue of the fact that the antisense polynucleotides used in the method are the opposite strands of the polynucleotides that encode the peptides. The inventions are distinct, however because the peptides are not used in the method of treating heart disease and are not necessary for that method. Therefore, the inventions are distinct.

20. The peptides of group II are related to the methods of decreasing mortality or morbidity in a subject with heart failure of group IX by virtue of the fact that the peptides are the substance which is inhibited in the method. The inventions are distinct, however because the peptides are not used in the method of decreasing mortality or morbidity in a subject with heart failure and are not necessary for that method. Therefore, the inventions are distinct.

21. The peptides of group II are related to the screening methods of groups X and XI by virtue of the fact that the polynucleotides used in the methods encode the peptides. The inventions are distinct, however because the peptides are not used in the screening methods and are not necessary for that method. Therefore, the inventions are distinct.

22. Inventions II and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the peptides could be used in a materially different process such as production of antibodies.

23. Inventions III, IV, VII, VIII, IX, X and XI are unrelated methods of use of the polynucleotides or their antisense strands. The methods all have different purposes and are not usable together. Thus, these inventions are patentably distinct.

24. Inventions III, V and XII are unrelated methods. Group III is a method of use of the polynucleotides and Groups V and XII are methods of using the peptides or antibodies. The methods all have different purposes and are not usable together. Thus, these inventions are patentably distinct.

25. Inventions III and VI are related only by virtue of the fact that the polynucleotides are involved in each group, group III is a method of use of the polynucleotides and group VI is a transgenic animal containing the polynucleotides. The two groups have different purposes and are not used together. Thus, these inventions are patentably distinct.

26. Inventions IV, VII, VIII, IX, X and XI are unrelated methods of use of the polynucleotides or their antisense strands. The methods all have different purposes and are not usable together. Thus, these inventions are patentably distinct.

27. Inventions IV, V and XII are unrelated methods. Group IV is a method of use of the polynucleotides and Groups V and XII are methods of using the peptides or antibodies. The methods all have different purposes and are not usable together. Thus, these inventions are patentably distinct.

28. Inventions IV and VI are related only by virtue of the fact that the polynucleotides are involved in each group, group IV is a method of use of the polynucleotides and group VI is a transgenic animal containing the polynucleotides. The two groups have different purposes and are not used together. Thus, these inventions are patentably distinct.

29. Inventions V and VI are unrelated inventions. The antibodies of group V have different purposes from the transgenic animal of Group VI and are not disclosed as being usable together. Thus, these inventions are patentably distinct.

30. The antibodies of group V are related to the method of gene therapy of group VII by virtue of the fact that the polynucleotides used in the method encode the peptides that are the cognate antigens for production of the antibodies. The inventions are distinct, however because the antibodies are not used in the method of gene therapy and are not necessary for that method. Therefore, the inventions are distinct.

31. The antibodies of group V are related to the method of treating a heart disease of group VIII by virtue of the fact that the antisense polynucleotides used in the method are the opposite strands of the polynucleotides that encode the peptides that are the cognate antigens for production of the antibodies. The inventions are distinct, however because the antibodies are not used in the method of treating heart disease and are not necessary for that method. Therefore, the inventions are distinct.

32. Inventions V and IX are unrelated inventions. The antibodies of Group V are not used in the methods of decreasing mortality or morbidity in a subject with heart failure of Group IX and have different purposes. Thus, these inventions are patentably distinct.

33. The antibodies of group V are related to the screening methods of Groups XI and XII by virtue of the fact that the peptides are the cognate antigens for production of the antibodies and are encoded by the polynucleotides. The inventions are distinct, however because the antibodies are not used in either screening method and are not necessary for either screening method. Therefore, the inventions are distinct.

34. Inventions VI and VII are related only by virtue of the fact that the polynucleotides are involved in each group, group VI is a transgenic animal containing the polynucleotides and group VII is a method of use of the polynucleotides. The two groups have different purposes and are not used together. Thus, these inventions are patentably distinct.

35. Inventions VI and VIII are related only by virtue of the fact that the polynucleotides are involved in each group, group VI is a transgenic animal containing the polynucleotides and group VIII is a method of use of the antisense strands of the polynucleotides. The two groups have different purposes and are not used together. Thus, these inventions are patentably distinct.

36. Inventions VI and IX are related only by virtue of the fact that the polynucleotides are involved in each group, group VI is a transgenic animal containing the polynucleotides and group IX is a method of use of the polynucleotides. The two groups have different purposes and are not used together. Thus, these inventions are patentably distinct.

37. The transgenic animal of group VI is related to the screening methods of Groups XI and XII by virtue of the fact that both involve the polynucleotides. The inventions are distinct, however because the transgenic animal is not used in either screening method and is not necessary for either screening method. Therefore, the inventions are distinct.

38. The methods of Inventions VII, VIII, IX, X, XI and XII are related in that each method requires the use of the polynucleotides. However, the steps and end points of the methods are wholly different and therefore Inventions VII, VIII, IX, X, XI and XII are patentably distinct.

39. In claims 2, 44-46 and 82-84 the presence of multiple polypeptide sequences and, in claims 3, 5-22, 24 and 25, the presence of multiple polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

40. Applicant is advised that a reply to this requirement must include an identification of SEQ ID NO: that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. This is not to be construed as an election of species, but rather an election between patentably distinct inventions. Evidence showing that the

sequences are somehow related such that one search query could cover all of them might be effective to negate this requirement.

41. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, search and divergent subject matter, restriction for examination purposes as indicated is proper.

42. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

43. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert A. Wax
Primary Examiner
Art Unit 1653